Welcome to today's FDA/CDRH Webinar

Thank you for your patience while we register all of today's participants.

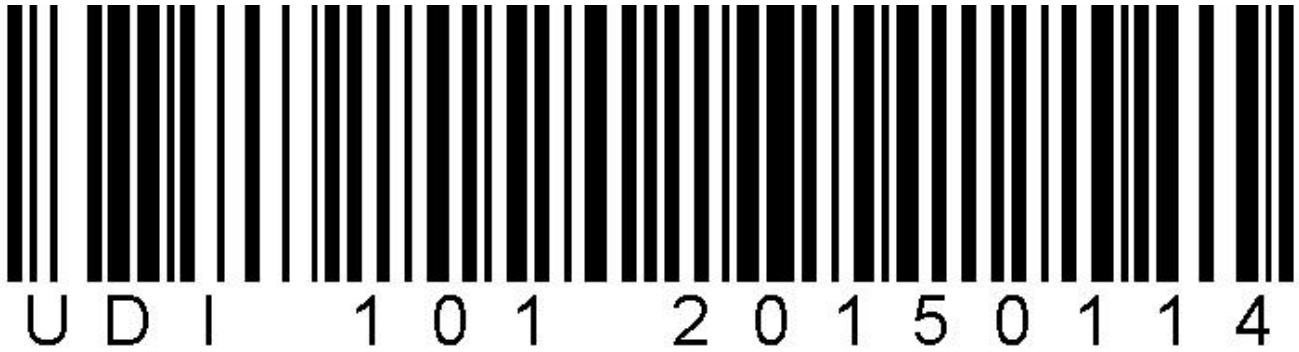
If you have not connected to the audio portion of the webinar, please do so now:

Dial: 1-800-369-3195

International Callers: 1-517-308-9090

Passcode: CDRH

The Unique Device Identification Program
January 14, 2015



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FDA\CDRH\OSB\Informatics Staff

Statutes and Regulation

- FDA Amendments Act, 2007
- FDA Safety and Innovation Act, 2012
- UDI Rule, September 24, 2013

Link: UDI Final Rule

Objectives of the UDI Program

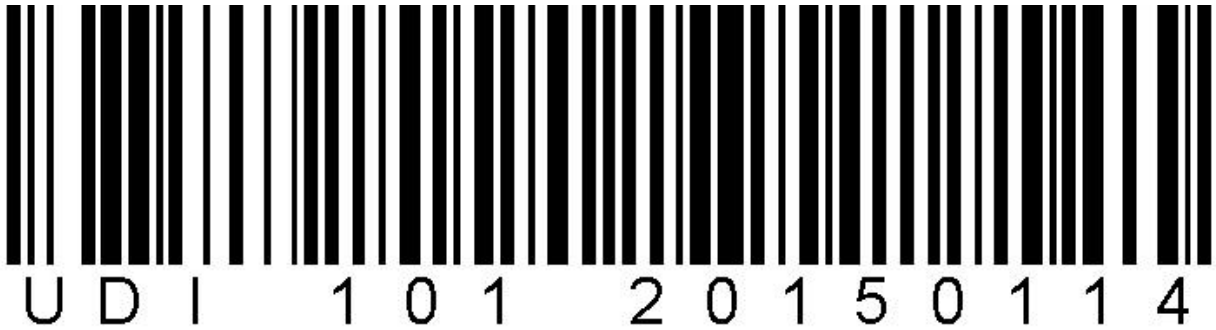
Establish a system to identify medical devices through distribution and use

- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Allow more accurate reporting, reviewing, and analyzing of adverse event reports
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries
- Enable more effectively managed medical device recalls

What is a UDI?

Code on the device label, packaging or, in some cases, on the device itself

Code is both plain text and machine readable format

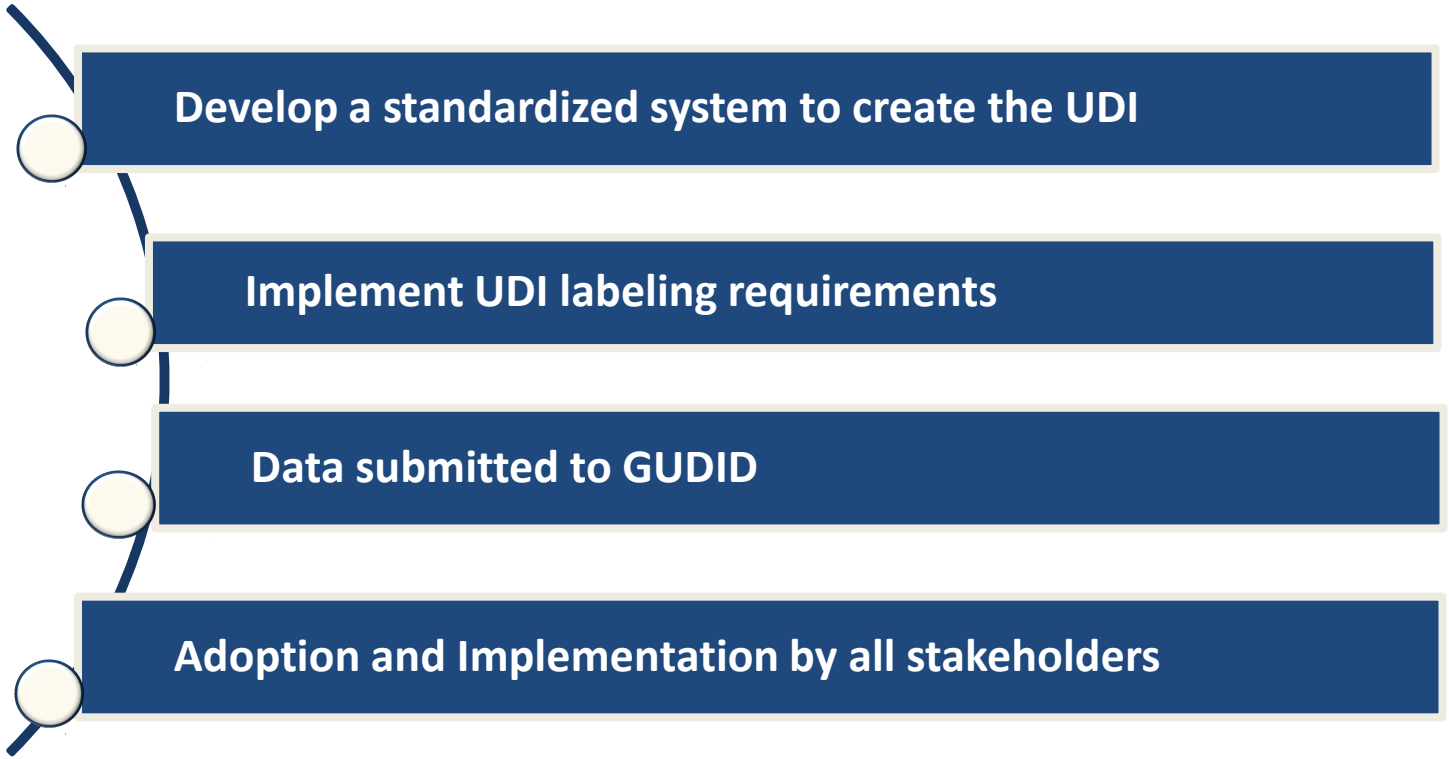


Unique Identification of Products is Not New

Example of a serialized National Drug Code (sNDC)

NDC		SERIAL NUMBER
55555 666 77	+	11111111111111111111
labeler code + product code + package code		unique, up to 20 characters

Four Steps to a Successful UDI Program



Products under UDI Rule

"Medical device" is defined by 21 USC 321(h)

UDI

Medical devices placed in commercial distribution after the applicable compliance date

Compliance Dates for UDI Requirements

Device	Label/GUDID/Date Format	Direct Mark (When Required)
Class III (including class III LS/LS)[1] **Devices licensed under the PHS Act**	September 24, 2014	Class III LS/LS devices must bear a permanent UDI by September 24, 2015 All other class III devices must bear a permanent UDI by September 24, 2016
Implantable (class II, class I & unclassified)	September 24, 2015	N/A
LS/LS[1] (class II, class I & unclassified)	September 24, 2015	September 24, 2015
Class II (other than I/LS/LS)	September 24, 2016	September 24, 2018
Class I or unclassified (other than I/LS/LS)	September 24, 2018	September 24, 2020

Link: Details on Compliance Dates

Exceptions and Alternatives

General exceptions under 21 CFR 801.30

FDA may grant an exception or alternative – on its own initiative or in response to a request.

FDA will post decisions on the UDI website.

Key General Exceptions

General exceptions from UDI labeling and data submission requirements include*

- Class I cGMP exempted devices
- Individual single-use devices sold and stored in a single package until removed for use
- IDEs or devices used solely for nonclinical use
- Devices intended solely for export from the US
- Individual devices in convenience kits
- Three year “grandfather”

*See 21 CFR 801.30 for full list of exceptions

Summary of Basic UDI Requirements

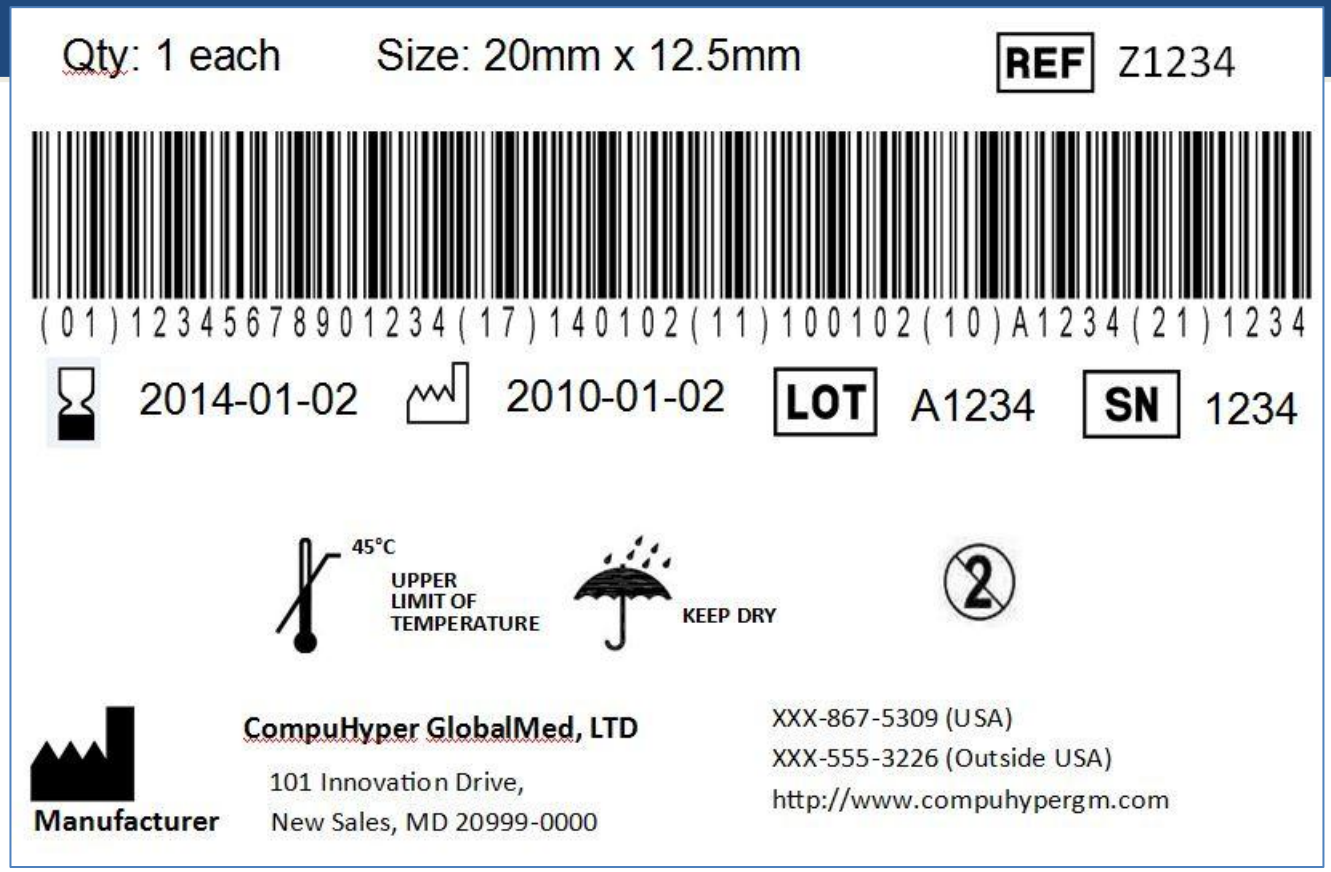
Device label and device package must bear a UDI

Key data for these devices must be submitted to GUDID

Dates on the device label must be in specified format

Label

"Label" means a "display of written, printed, or graphic matter upon the immediate container of any article…"



Labeler

Labeler is responsible for UDI requirements

Defined under 21 CFR 801.3 as

any person who causes a label to be:

- Applied to a device with the intent that the device will be commercially distributed (was in interstate commerce); or
- Replaced or modified with the intent that the device will be commercially distributed

Issuing Agency (IA)

An issuing agency operates a system for issuing UDIs to labelers.

The UDI rule requires all UDIs to be issued under a system operated by an FDA-accredited issuing agency.

FDA accreditation requires that the issuing agency's system conforms to certain international consensus standards.

Accreditation is granted for an initial term of 3 years and may be renewed upon submission and FDA approval of a renewal application and may be revoked by the FDA

What is a UDI?

Is a unique numeric or alphanumeric code;

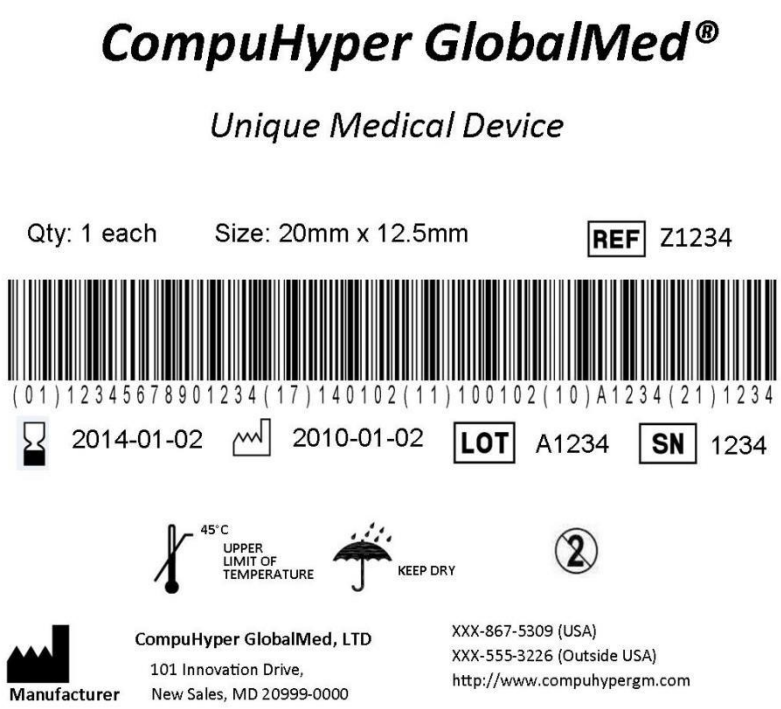
Displayed in both human readable (plain text) and machine readable (AIDC) form;

that consists of two parts:

Device Identifier (**DI**)	Production Identifier(s) (**PI**)

Unique Device Identifier (UDI)

UDI = DI + PI



Device Identifier (DI)

Device Identifier (DI) is a mandatory, fixed portion of a UDI that identifies (1) the labeler and (2) the specific version or model of a device.

Production Identifier (PI)

Production Identifier(s) (PI) is a conditional, variable portion of a UDI

- Not required for class I devices

Includes (when on the device label):

- lot, batch or serial number,
- expiration date or date of manufacture
- HCT/P's regulated as devices: the required distinct identification code.

Date Format

Applies to dates on label

- Expiration date
- Manufacturing date
- Any other dates on the label intended to be brought to the attention of the user

Format:
year-month-day
Ex: 2014-01-30

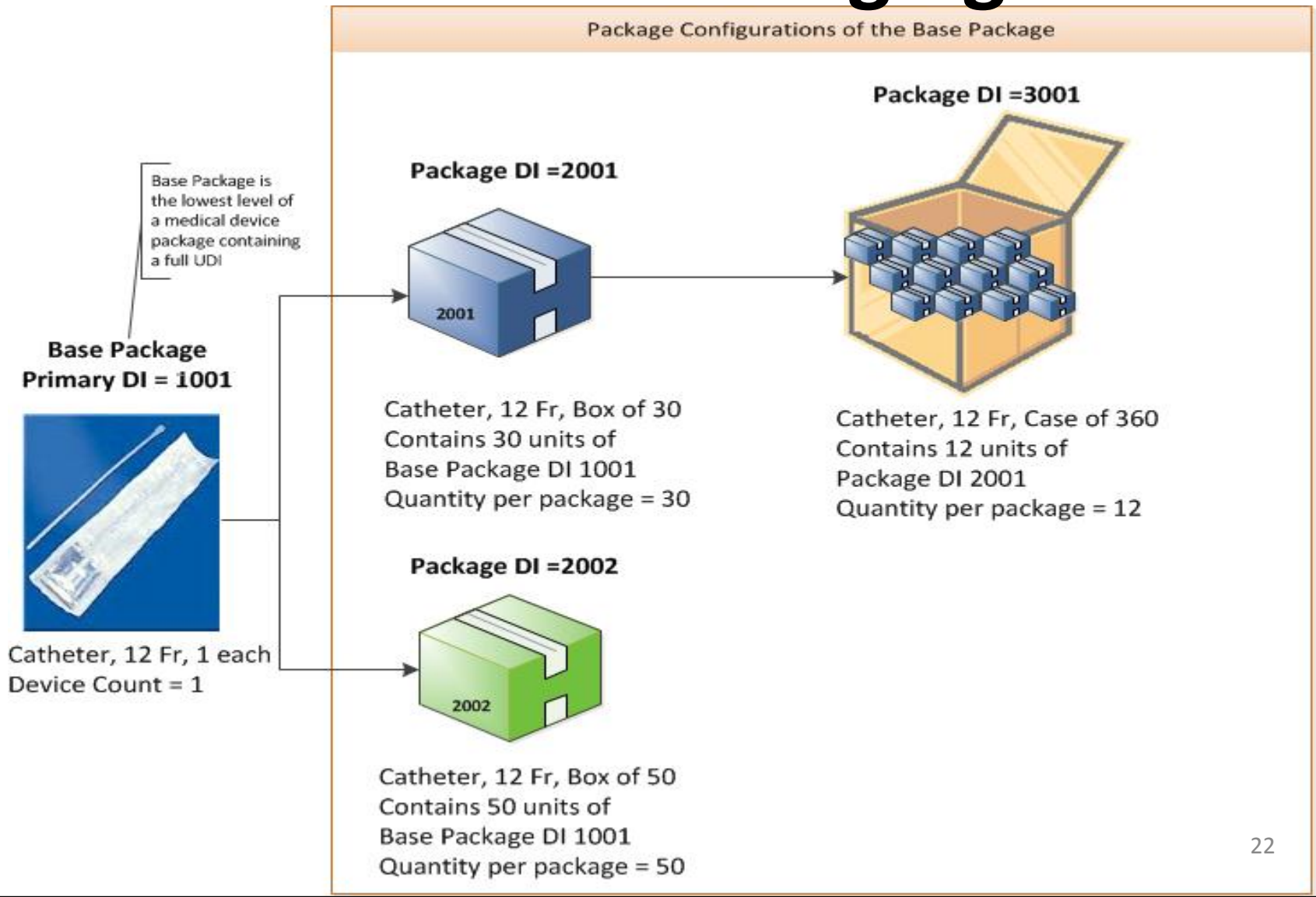
General UDI compliance dates apply

Device Package

It contains a fixed quantity of a particular version or model of a device

Each level of packaging requires a different UDI

Levels of Packaging



These are Not Packaging and Do Not Require a UDI

UDI System

Label

Unique device identifier (UDI)

Data

Submitted to the Global Unique Device Identification Database (GUDID)

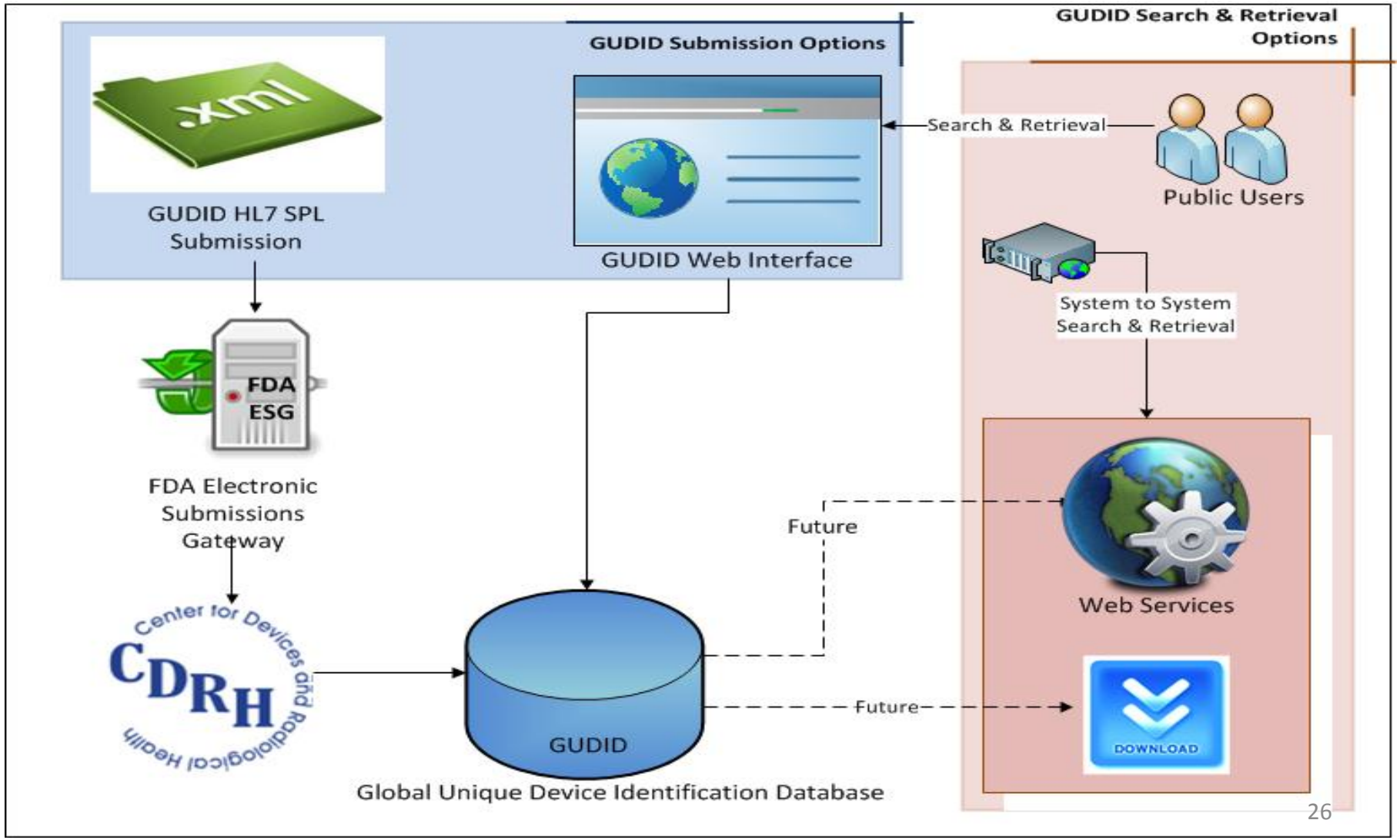
GUDID Global Unique Device Identification Database

Repository of key device identification information

Contains ONLY the DI; PIs are not submitted to or stored in the GUDID

Contains only PI flags to indicate which PIs are on the device UDI

GUDID Overview



GUDID DI Information

Device Information

Device Identifier (DI) Information

Issuing Agency: *	Primary DI Number: *	Device Count: *	Unit of Use DI Number:
HIBCC	wsDIOverview	1	

Labeler DUNS Number: *	Company Name:	Company Physical Address:
039169488	Safeway Grocery	4551 Forbes Blvd, Lanham, MD 207064389

Brand Name: *	Version or Model Number: *	Catalog Number:
DIOverview	123456	123456

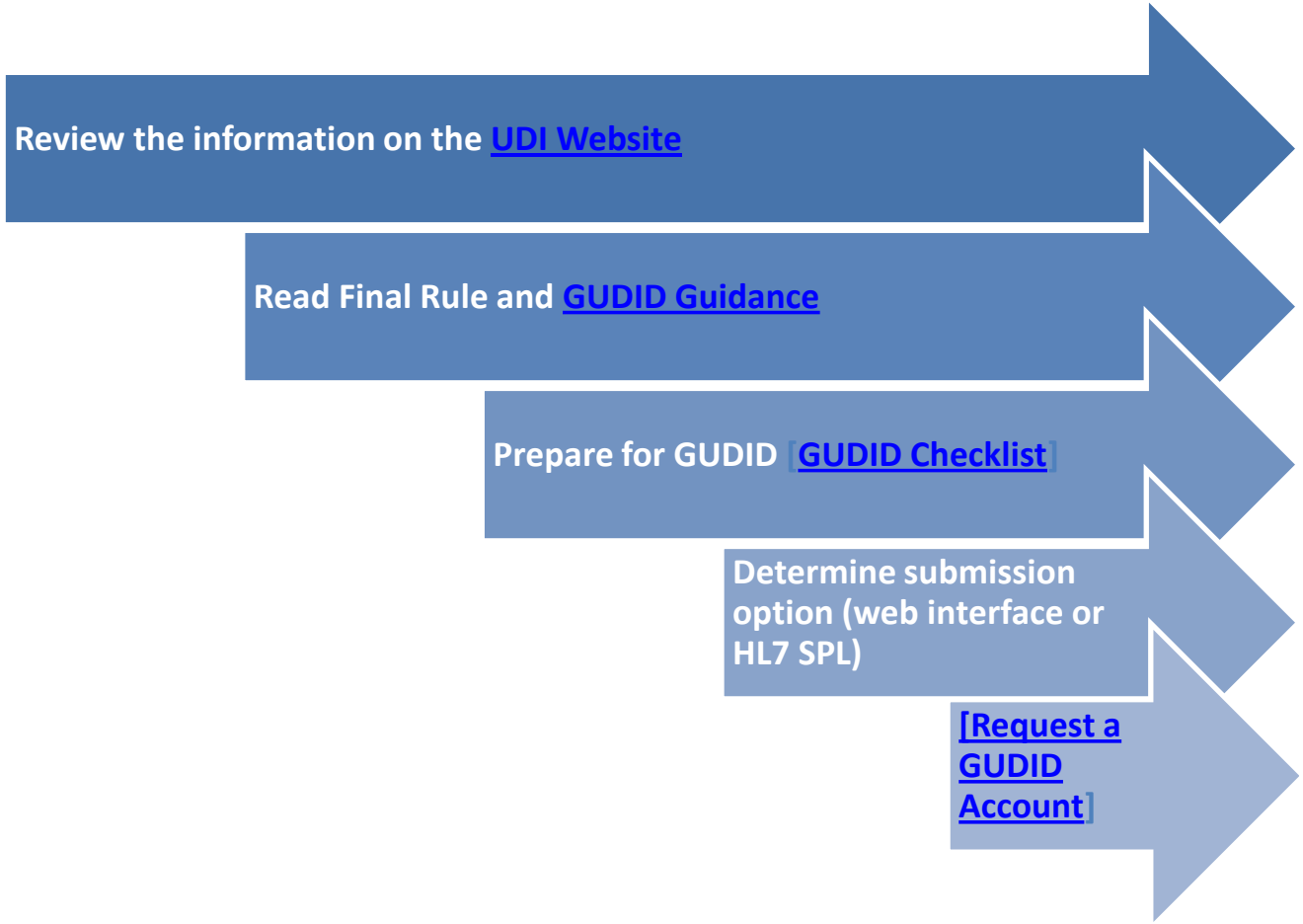
Device Description (max 2000 characters):

DIOverviewRecord

Commercial Distribution

DI Record Publish Date (yyyy-mm-dd): *	Commercial Distribution End Date (yyyy-mm-dd):	Commercial Distribution Status:
2014-05-09		In Commercial Distribution

Recommended Preparatory Steps to Opening a GUDID Account



Additional Resources

FDA Webinar: Device Identifier Record

FDA Webinar: GUDID HP7 SPL Submission Option Overview

GUDID Database Elements Reference Table

UDI Issuing Agencies

Questions?

FDA UDI Help Desk:
www.fda.gov/udi

Slide Presentation, Transcript and Webinar Recording will be available at:
www.fda.gov/CDRHWebinar
Under Heading: Unique Device Identification (UDI) System